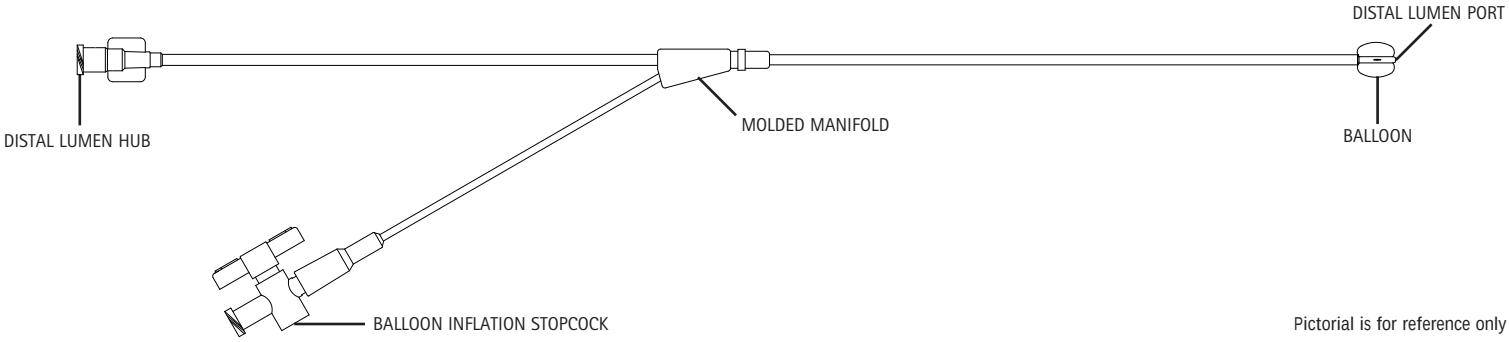
Corodyn™ P1

Monitoring Wedge Pressure Balloon Flotation Catheter



Pictorial is for reference only

Table 1

French Size (Outer Diameter mm)	Introducer Size Required	Useable Length	Maximum Balloon Inflation Capacity	Nominal Inflated Balloon Diameter	Recommended Guidewire Size	Proximal Port Location
5 F (1.65 mm)	6 F	60 cm	0.75 cc	8 mm	0.025 in. (0.63 mm)	N/A
5 F (1.65 mm)	6 F	110 cm	0.75 cc	8 mm	0.025 in. (0.63 mm)	N/A
6 F (1.98 mm)	7 F	60 cm	1.25 cc	10 mm	0.025 in. (0.63 mm)	N/A
6 F (1.98 mm)	7 F	110 cm	1.25 cc	10 mm	0.025 in. (0.63 mm)	N/A
7 F (2.31 mm)	8 F	110 cm	1.5 cc	12 mm	0.038 in. (0.96 mm)	N/A

DESCRIPTION

Monitoring wedge pressure balloon flotation catheters are used for:

- Assessment of hemodynamic status, including intra-cardiac and pulmonary artery pressure monitoring, and sampling of mixed venous blood for the assessment of oxygen transport in patients with:
  - Acute heart failure
  - Severe hypovolemia
  - Complex hemodynamic situations, for example: fluid management in an acute burn patient; severe septic shock; Adult Respiratory Distress Syndrome; peri-operative management of patients with severe cardio-respiratory disease, or with major disturbances of fluid balance
- Blood sampling and solution infusion

Monitoring wedge pressure balloon flotation catheters may be inserted without fluoroscopy, guided by continuous pressure monitoring. However, they are radiopaque so that fluoroscopy can be used to guide insertion or to verify position if desired.

Monitoring wedge pressure balloon flotation catheters contain two lumens for the following purposes:

- **Distal** - Terminates at the tip of the catheter and is used for the measurement of pulmonary artery pressure, pulmonary capillary wedge pressure, blood sampling from the pulmonary artery, and solution infusion.
- **Balloon** - Provides a means for inflating and deflating the balloon located near the tip of the catheter, facilitating catheter advancement and measurement of pulmonary capillary wedge pressure.

Catheter body made from PUR material.

INDICATIONS FOR USE

The monitoring wedge pressure balloon flotation catheter is designed for sampling blood for oxygen levels and measuring pressures in the right heart, including central venous pressure, right ventricular pressure, pulmonary artery pressure and pulmonary artery wedge pressure. It may also be used to sample blood and measure pressure in any chambers that can be entered from the right heart.

CONTRAINDICATIONS

Conditions in which contraindications to the use of pulmonary artery catheters exist: right-sided endocarditis; mechanical tricuspid (or pulmonic) valve prosthesis; presence of thrombus or tumor in right heart chamber.

Relative contraindications include: recently inserted transvenous pacemaker, bifascicular heart block, coagulopathy, frequent dysrhythmias, history of pulmonary stenosis.

READ ALL INSTRUCTIONS, WARNINGS AND CAUTIONS CAREFULLY PRIOR TO USE.

CAUTION: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

RISKS

All invasive procedures involve some patient risks. The potential risks and benefits of this catheter use should be carefully considered for each patient prior to insertion and at intervals while the catheter remains in place.

Patients with severe pulmonary hypertension, especially if accompanied by right ventricular failure; severe hypoxemia; left bundle branch block; uncontrolled congestive heart failure; uncontrolled arrhythmias; renal dysfunction, or history of radiocontrast agent reaction maybe at higher risk.

Severe, sometimes fatal, complications have been associated with the use of pulmonary artery catheters. These complications include arrhythmias, knotting of the catheter, and pulmonary artery rupture.

For single use only | STERILE EO NONPYROGENIC — Contents sterile in unopened, undamaged package | Manufacture Date | Expiration date | REF Reorder Number | LOT Lot number | 15° C – 30° C Store between 15° - 30° C (59° - 86° F).

Do not resterilize | See instructions for use | Keep away from sunlight | Keep dry | LATEX Contains Natural Rubber Latex | PHT DEHP Contains DEHP | Do not use if package is damaged

Rx only

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Strict adherences to the foregoing instructions and the awareness of possible complications have been the most significant factors in reducing the incidence of complications.

The risks of pulmonary artery catheters are divided into five categories:

1. **Perforation of the Pulmonary Artery**
   Factors associated with the development of fatal pulmonary artery rupture during use of this catheter include pulmonary hypertension, advanced age, cardiac surgery with hypothermia and anticoagulation, and distal catheter tip migration, arteriovenous fistula formation or other vessel damage.

   Extreme care should be used during the measurement of pulmonary artery wedge pressure in patients with pulmonary hypertension.
2. **Pulmonary Infarction**
   Tip migration with spontaneous wedging, air embolism, and thromboembolism can lead to this complication.
3. **Cardia Arrhythmias**
   Arrhythmias may occur during catheter insertion or removal, but are usually transient and self-limited. Premature ventricular contractions are the most commonly observed arrhythmia; however ventricular tachycardia and atrial and ventricular fibrillation have also been reported. Lidocaine injection may be helpful in decreasing the incidence of ventricular arrhythmias during catheterization. ECG monitoring and the immediate availability of antiarrhythmic drugs and defibrillating equipment are recommended.
4. **Knotting**
   If the right ventricular pressure waveform remains after advancing the catheter 15 cm from where it was first observed, the catheter may be looped in the right ventricle. This may cause twisting or knotting of the catheter. Deflate the balloon and withdraw the catheter to the right atrium. Then inflate the balloon, advance the catheter to the pulmonary arterial wedge, and deflate the balloon again.

   Sometimes the knot can be resolved by insertion of a suitable guidewire and manipulation of the catheter under fluoroscopy.

   If the knot does not include any intracardiac structures, the knot may be gently tightened and the catheter withdrawn through the site of entry.
5. **Sepsis/Infection**
   Increased risks of septicemia and bacteremia can be associated with blood sampling, the infusing of fluids, and catheter-related thrombosis. Preventive measures should be taken to guard against infection, including the use of sterile technique, application of topical antibiotic ointment, and frequent changing of sterile dressings.
6. **Other Complications**
   The following may occur as a result of use of this device:

   Bundle branch block, complete heart block, tricuspid or pulmonary valve damage, thrombocytopenia, pneumothorax, thrombophlebitis and thrombosis. Physicians should identify latex sensitive patients and be prepared to treat allergic reactions promptly.

WARNINGS

- Pulmonary complications may result from improper inflation technique.
- To avoid damage to the pulmonary artery and possible balloon rupture, do not inflate balloon above the recommended volume as stated in Table 1. Exceeding this volume will not appreciably increase the diameter of the balloon and may increase the possibility of balloon rupture.
- Filtered CO_2 must be used to inflate the balloon if there is a possibility that balloon rupture would result in air embolus in the heart or arterial circulation. Liquids must not be used as a balloon inflation medium. If the balloon should inadvertently rupture, CO_2 is rapidly absorbed into the blood, significantly reducing the possibility of air embolus.

  Due to arm movement, malposition and perforation may occur more frequently when a transbrachial approach is used.

PRECAUTIONS

- To avoid damage to the catheter or balloon when a cut down is used, it is recommended that a vessel dilator or disposable vein guide be used. Never use forceps on the catheter.
- Use catheter only with recommended introducer and guidewire sizes (see Table 1).
- Always deflate the balloon prior to withdrawing the catheter.
- To minimize ventricular irritability, inflate the balloon before the catheter reaches the right ventricle.
- If CO_2 is used as inflation medium, care must be taken to compensate for diffusion through the latex balloon. When catheter insertion is not complete after 2 to 3 minutes of balloon inflation, completely deflate the balloon by removing the balloon syringe and opening the stopcock to vent the balloon lumen. Reinflate with recommended volume of CO_2 to advance the catheter.
- A flow directed catheter may migrate into the distal pulmonary artery and spontaneous wedging may occur. To detect the occurrence of spontaneous wedging, pulmonary artery pressure should be monitored continuously.
- Do not leave the catheter in the pulmonary capillary wedge position for prolonged periods of time. Always deflate the balloon after measurement of pulmonary capillary wedge pressure.
- It is generally recommended that the catheter not be left in the patient for longer than three days.
- A continuous drip or an intermittent flush should be used to maintain patency of lumen.
- Do not flush the catheter when obtaining wedge pressure measurements in the pulmonary artery. Doing this increases the danger of rupture of the pulmonary artery.
- Infusion of viscous solutions such as whole blood is not recommended.
- Damping of the pressure tracing may indicate the formation of a blood clot at the distal tip. Do not flush catheter if blood cannot be aspirated, as this may cause pulmonary extravasation.
- To determine pulmonary capillary wedge pressure, inflate balloon slowly, stopping when pulmonary artery waveform changes to a pulmonary capillary wedge pressure waveform. Passively deflate balloon after completing measurement.

INSTRUCTIONS FOR USE

CATHETER INSPECTION AND TESTING:

Monitoring wedge pressure catheters are supplied in sterile packages. Inspect the package. Do not use the catheter if there is any evidence that the package has been punctured or that the catheter has been damaged. When using with other medical equipment, refer to the equipment's Instructions for Use.

1. Remove the catheter from the package using aseptic technique.
2. Inflate the balloon to recommended capacity (see Table 1) and immerse the balloon in sterile room temperature water or saline. If there is any evidence of air bubbles escaping the balloon or if the balloon will not remain inflated, do not use the catheter.
   Note: Never use liquid for balloon inflation.
3. Flush all of the catheter lumens with a sterile solution of heparinized saline or 5% dextrose and water to insure patency and remove air.

CATHETER INSERTION: Use Aseptic Technique.

The following instructions are general for informational purposes and are only provided as an aid to the physician:

1. Introduce the catheter by cut down or by percutaneous technique through a suitable needle or sheath.
2. Gently advance the catheter into the superior or inferior vena cava. Entry of the catheter tip into the thorax is associated with increased respiratory fluctuation in pressure.

   Note: Should the catheter require stiffening during insertion, slowly perfuse the catheter with 5 mL or 10 mL cold sterile saline or 5% dextrose as the catheter is advanced through a peripheral vessel.
3. When the catheter is near the junction of the right atrium and the superior or inferior vena cava, the tip has been advanced approximately 40 cm from the right or 50 cm from the left antecubital fossa, 15 to 20 cm from the jugular vein, 10 to 15 cm from the subclavian vein or about 30 cm from the femoral vein. Using a volume limited syringe, inflate the balloon to the recommended volume (see Table 1).
4. Under continuous pressure and EKG monitoring, carefully advance the catheter. It will usually pass within 10 to 20 seconds through the right atrium, the right ventricle, into the pulmonary artery and into the pulmonary capillary wedge position.
5. If after advancing the catheter with the balloon inflated, pulmonary artery pressure is not obtained, deflate the balloon, withdraw the catheter into the right atrium (confirm by pressure monitoring or fluoroscopy) and repeat the procedure.
   Note: Failure of a balloon flotation catheter to enter the right ventricle or pulmonary artery is rare, but may occur in patients with an enlarged atrium or ventricle, particularly if the cardiac output is low or in the presence of tricuspid incompetence. Deep inspiration by the patient during advancement may facilitate passage.
6. Pulmonary artery pressure will be observed as soon as the balloon passes through the pulmonary valve.
7. Once the balloon becomes lodged in the wedge position, as noted on the pressure monitor, passively deflate the balloon.
   Note: After deflation of the balloon, the catheter tip may recoil toward the pulmonic valve and slip back into the right ventricle, requiring repositioning of the catheter.